

Remarks

The Examiner is thanked for the Office Action mailed 01/14/03. The rejections and new claims are discussed in sequence below. Note that new claims 44, 45 merely specify that the biopolymers are polynucleotides in a similar manner as original claim 2.

Indefiniteness Rejections

The Examiner first raised a number of rejections under 35 U.S.C. 112, second paragraph (indefiniteness). On the question of what is required by 35 USC § 112, second paragraph, the Federal Circuit's discussion in Miles Laboratories Inc. v. Shandon Inc. 27 USPQ 1123 @ 1126 (Fed.Cir. 1993) is instructive:

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. *Orthokinetics*, 806 F.2d at 1576. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. *Hybritech*, 802 F.2d at 1385. The degree of precision necessary for adequate claims is a function of the nature of the subject matter. *Id.*"

Further, M.P.E.P. § 2173 outlines the same approach when considering the second paragraph of 35 USC § 112. Each of the 35 U.S.C. 112, second paragraph rejections will now be discussed bearing in mind the above direction.

The Examiner first rejected claims 6, 28 on the basis of the use of "in accordance with the retrieved biological function data". The Examiner stated that this limitation appears to intend that the retrieved biological function data in some way directs the processor to read the array or process information in a different manner based upon the information retrieved. The Examiner then goes on to state that the claims do not make clear what positive action step is to occur nor the criteria determining whether or not such an action will or will not occur. The Examiner is correct that the limitation "in accordance with the retrieved biological function data" requires that the retrieved biological function data in some way directs the processor to read the array or process information in a different manner based upon the information retrieved. The claim is not limited to the details of how the array reading or processing of information obtained from reading the array is to occur. If one uses the retrieved biological function data to control reading of the array or process

information obtained from reading the array, they fall within the scope of the claim regardless of the details of how they use the retrieved biological function data to accomplish this purpose. Thus, one of skill clearly knows when they fall within these claims and they therefore “reasonably apprise those skilled in the art of the scope of the invention” and “§ 112 demands no more”. Accordingly, this rejection of claims 6, 28 should be withdrawn.

Claim 10 was rejected for lack of antecedent basis for the use of “biopolymer identity data obtained”. In claim 10 the biopolymer identity data is obtained using the identifier signal. In an effort to make the claim clearer it has now been amended to recited “or communicating a biopolymer identity data obtained using the identifier signal”. Consequently, it is believed that this rejection should now be withdrawn in view of this clarifying amendment.

The Examiner next rejected claim 11 as confusing for reciting “obtaining a communication address of the remote station using the identifier signal”. The Examiner stated that it was not clear if the communication address was embedded or encoded within the identifier or if the identifier provides a direction to retrieve the communication address (and if so, how or from where this information is to be retrieved). Page 4 lines 9-14, and page 18 lines 24-29 make it clear that either possibility is encompassed within the invention. Thus, one of skill in the art has no difficulty in understanding that if they obtain a communication address of the remote station using the identifier signal (regardless of which method or the details of how it is done) they fall within the language “obtaining a communication address of the remote station using the identifier signal”. Thus, one of skill clearly knows when they fall within these claims and they therefore “reasonably apprise those skilled in the art of the scope of the invention” and “§ 112 demands no more”. Accordingly, this rejection should be withdrawn.

The Examiner next rejected claim 12 on the basis that it appeared incomplete. In an effort to further clarify this claim it has been amended to additionally recite “and receiving the biological function data in response”. Such a feature is recited, for example, on page 4, lines 2-3 of the present application. The Examiner next stated that the limitation of claim 12 did not appear to further limit the method of claim 9. However, claim 12 is dependent upon claim 10 which states that “the biological function data is retrieved by communicating to the remote station the identifier signal,

or communication a biopolymer identity data obtained using the identifier signal, and receiving the biological function data in response". Thus, claim 12 presents two alternatives for retrieving the biological function data while claim 12 states that the method comprises the specified alternative of "the biological function data is retrieved by communicating the identifier signal to the remote station and receiving the biological function data in response". Accordingly, claim 12 does further limit claim 9.

In view of the above, the rejection of claim 12 as amended should now be withdrawn.

The Examiner also went on to reject claim 13 on the basis that the "memory carrying multiple identifiers in association" would appear to be an implicit limitation of claim 9. However, neither claim 10 nor 9 specifically recite that the memory is one carrying multiple identifiers and accordingly this language is an additional limitation.

The Examiner next rejected claim 26 as being a method limitation which did not further limit the apparatus of claim 25, and similarly rejected claims 31-33 in relation to claim 30. Each of the dependent claims 26, 31-33 specify further details of what the "processor" must do. A processor is hardware which is constructed or programmed to execute all the steps required of it as per the definition on page 9, lines 25-29. Accordingly, the limitations being added by the dependent claims are limitations on the processor itself. These limitations "reasonably apprise" one of skill what the processor must do and "§ 112 demands no more". Therefore, the present rejection should be withdrawn.

The Examiner next rejected claim 31 on the basis that it was "confusing" in reciting "along with an indication of a suspected feature error". A feature error is an error in an array feature. An "error" is defined in Merriam-Webster's OnLine Dictionary (available at [www.merriam.com](http://www.merriam.com)) as"

"Main Entry: **er·ror**

**1 a :** an act or condition of ignorant or imprudent deviation from a code of behavior **b :** an act involving an unintentional deviation from truth or accuracy **c :** an act that through ignorance, deficiency, or accident departs from or fails to achieve what should be done: as..."

Thus a "feature error" is just some deviation of the feature from what should have been obtained. Furthermore, different types of "feature errors" were described on

page 5, lines 4-7 of the present application as including “errors in dimensions (such as total area), location, presence (for example, an expected feature is missing), or amount of biopolymer present at a feature”. In view of both of these one of skill in the art is “reasonably apprised” that if they communicate “an identification of the feature along with an indication of a suspected feature error” (deviation in the feature), they fall within the referenced language of claim 31. As “§ 112 demands no more”, this rejection should be withdrawn.

#### Anticipation Rejections

The Examiner next rejected claims 1-13, 25-30, 32-33 as being anticipated by Muraca (U.S. Patent Publication No. 2002/0168639) and also by Doung et al. (U.S. Patent Publication No. 2002/0177135) under 35 U.S.C. 102(e).

Claims 1-13, 25-27, 29 have been amended to recite that “the retrieved biological function data comprises information on the function of a target of the array, or its complement, or the gene from which either originated” (as recited, for example, on page 16, lines 18-25). Note also that new claim 39 specifically requires the retrieved biological information to include the gene information (whereas claim 1 recites that either the target function or gene information may be present). Neither Muraca nor Doung et al. disclose retrieving any of the foregoing types of data. Accordingly, the rejection of these claims should now be withdrawn.

Claim 28 has been rewritten in independent form and requires, among other limitations that “the processor either controls reading of the array or processes information obtained from reading the array, in accordance with the retrieved biological function data”. The Examiner does not allege that Muraca or Doung et al. disclose the foregoing limitation, nor do they. Accordingly, since every claimed element is not found in Muraca or Doung et al. this rejection should be withdrawn. If the Examiner is of the view that such a limitation is in Muraca or Doung et al. she is asked to specifically point to it in the reference.

Claims 30 (and 32, 33 which depend therefrom) require, among other elements:

An apparatus for using an addressable array of biopolymers on a substrate, comprising

- (a) an array reader which reads the array following exposure to a sample;
- (b) a reader which reads an identifier carried on an array substrate or an array housing, as an identifier signal;
- (d) a processor which:
  - retrieves feature characteristic data for the array from a memory based on the read identifier signal, and
  - communicates feature characteristic data for the array to a remote location in association with an identification of the feature.

Note that the processor both retrieves feature characteristic data, and communicates feature characteristic data to a remote location. The Examiner alleges that Muraca can retrieve information from an information database using the identifier, and that the information can be communicated by e-mail or wireless communication. Even assuming this is correct, nothing in the foregoing or elsewhere in Muraca discloses an apparatus for using an addressable array which both retrieves feature characteristic data and communicates feature characteristic data to a remote location. Paragraphs 34, 144, and 181 in Muraca explain this situation as follows (from paragraph 34):

“In a further embodiment, access is in the form of an identifier identifying the microarray and a password for accessing an electronic database in which tissue information is stored.”

That is, the apparatus of Muraca may retrieve tissue information from the database but nothing in Muraca additionally discloses additionally that same apparatus (not a different apparatus) communicating feature characteristic data for the array to a remote location.

Similarly, with Doung et al. the Examiner alleges that reference discloses the reader apparatus which can communicate “data assay results, barcode information, etc.” to a remote location. The Examiner references a number of portions of Doung et al. the most pertinent on this aspect being paragraph 356 which reads as follows:

“In a preferred embodiment, the devices of the invention include components for the communication of data, assay results, patient information, etc. to an off-device location. Thus, for example, one or more modems (including both telephone and cable modems), internet cards, infrared ports, etc. may be included in the devices to allow the

transmission of data and other relevant information (barcode information, assay conditions and protocols, operator identification, time stamps, etc.) to a remote location such as a general information repository, hospitals, doctor's offices, epidemiology centers, pharmacies, government centers, insurance providers, etc."

The above merely refers to transmitting data relating to the usage of the array. Nowhere in the above, or elsewhere in Doung et al., is there reference to a processor which retrieves feature characteristic data for the array from a memory based on the read identifier signal, and communicates feature characteristic data for the array to a remote location in association with an identification of the feature.

Accordingly, this rejection based on anticipation under 35 U.S.C. 102(e) over Muraca or Doung et al. should be withdrawn in relation to claim 30 (and 32, 33).

New claims 40-43 are dependent on claim 30 and should be allowed for the reasons discussed above. Additionally, these new claims add further limitations on the requirements for particular types of feature characteristic data as described on, for example, page 5, lines 3-10 and page 16, lines 18-25. Neither Muraca nor Doung et al. disclose a processor which communicates any of the foregoing types of information to a remote location (in addition to retrieving feature characteristic data) in an apparatus which also includes the array reader and identifier reader, as required by these claims. Accordingly, these claims should be allowable over the cited references for this additional reason.

The Examiner next rejected claims 1-3, 5, 7-12, 25, 27, 29-30, and 32-33 under 35 U.S.C. 102(b) as being anticipated by Schembri (GB 2,319,833).

Claims 1-3, 5, 7-12, 25, 27, and 29. By virtue of the amendment to claims 1, 9, 25, all of these claims now require that "the retrieved biological function data comprises information on the function of a target of the array, or its complement, or the gene from which either originated". The first full paragraph on page 11 of Schembri deals with what is communicated and none of the foregoing types of biological function data are disclosed in that paragraph (or elsewhere). Accordingly, this rejection of these claims as amended, should now be withdrawn.

As to claim 30 (and 32-33 which depend thereon), as pointed out above that claim requires, among other elements:

An apparatus for using an addressable array of biopolymers on a substrate, comprising

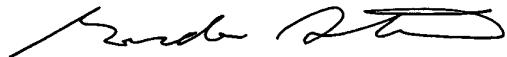
- (a) an array reader which reads the array following exposure to a sample;
- (b) a reader which reads an identifier carried on an array substrate or an array housing, as an identifier signal;
- (d) a processor which:
  - retrieves feature characteristic data for the array from a memory based on the read identifier signal, and
  - communicates feature characteristic data for the array to a remote location in association with an identification of the feature.

As discussed above, the processor in the apparatus must both retrieve the recited feature characteristic data and communicate the recited feature characteristic data. Nothing in Schembri, and particularly the first full paragraph on page 11 of that reference, discloses such a feature. Accordingly, this rejection in relation to claims 30 (and 32-33) should be withdrawn.

In addition to the above, claim 33 further requires that “the processor additionally obtains a communication address for the remote location using the identifier signal and communicates the feature characteristic data to the remote location using the communication address”. No such feature is disclosed on pages 6 or 11 of Schembri or elsewhere. Accordingly, for this additional reason this rejection of claim 33 should be withdrawn.

In view of the above amendments and discussion, it is believed that claims 1-13, 25-33, and 37-45 are now in condition for allowance. If the Examiner is of the view there are any outstanding issues which might be resolved by means of a telephone conference, she is invited to call Gordon Stewart at (650)485-2386.

Respectfully submitted,



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10010009-1 1<sup>st</sup> Response 04/14/03